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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,578	11/13/2003	Sanjay Awasthi	124263-1006	8252

7590 09/22/2005

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,578	AWASTHI ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 4 in part, 5-8 and 47, as specifically drawn to a method of preparing a proteoliposome comprising the steps of contacting a liposome with an effective portion of RLIP76 to create a proteoliposome, further comprising adding the proteoliposome to a toxic compound, wherein the toxic compound resides in an organism, mammalian cell or transfected mammalian cell, classified in class 264, subclass 4.1.

II. Claims 1-3, 4 in part, 5-8 and 47, as specifically drawn to a method of preparing a proteoliposome comprising the steps of contacting a liposome with an effective portion of RLIP76 to create a proteoliposome, further comprising adding the proteoliposome to a toxic compound, wherein the toxic compound resides in a bioreactor, soil, water, spill, process waste stream, manufacturing waste, chemical waste, laboratory waste or hospital waste, classified in class 264, subclass 4.1.

III. Claims 9-29 and 48-52, as specifically drawn to a proteoliposomal composition comprising a liposome and an effective amount of RLIP76, classified in class 536, subclass 23.1.

IV. Claims 30-33, 34 in part, 35 and 43-46, as specifically drawn to a method of reducing the effects and/or enhancing resistance of cells to a toxic compound, classified in class 424, subclass 450.

V. Claims 30-33, 34 in part and 35, as specifically drawn to a method of reducing the effects of ionizing radiation comprising adding a proteoliposome to a material with ionizing radiation, wherein the material is soil, water, spill, process waste stream,

manufacturing waste, chemical waste, laboratory waste or hospital waste, classified in class 435, subclass 262.

VI. Claims 36-42, as specifically drawn to a kit prepared for using a proteoliposomal composition, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups III and VI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. In the instant case, the proteoliposomal composition comprising a liposome and an effective amount of RLIP76 (Group III) and the kit prepared for using the proteoliposomal composition (Group VI) contain structurally distinct material such that one invention could not be interchanged with the other. For example, the kit includes an instructional pamphlet, which does not appear to be required in the proteoliposomal composition. For these reasons the inventions of Groups III and VI are patentably distinct.

The inventions of Groups III and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups III and VI. As such, each invention would require different searches and the consideration of different patentability issues.

The inventions of Groups I-II and IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method of preparing a proteoliposome comprising the steps of contacting a liposome with an effective portion of RLIP76 to create a proteoliposome, further comprising adding the proteoliposome to a toxic compound, wherein the toxic compound resides in an organism, mammalian cell or transfected mammalian cell (Group I), the method of preparing a proteoliposome comprising the steps of contacting a liposome with an effective portion of RLIP76 to create a proteoliposome, further comprising adding the proteoliposome to a toxic compound, wherein the toxic compound resides in a bioreactor, soil, water, spill, process waste stream, manufacturing waste, chemical waste, laboratory

waste or hospital waste (Groups II), the method of reducing the effects and/or enhancing resistance of cells to a toxic compound (Group IV), and a method of reducing the effects of ionizing radiation comprising adding a proteoliposome to a material with ionizing radiation, wherein the material is soil, water, spill, process waste stream, manufacturing waste, chemical waste, laboratory waste or hospital waste (Group V) are unrelated as they comprise distinct steps and utilize different materials which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for the method of producing a proteoliposome and treating differ significantly for each of the materials. For producing a proteoliposome, the process further comprises adding the proteoliposome to a toxic material which could reside in a cell/organism or in chemical waste/laboratory waste. For treatment, the process comprises adding the proteoliposome to a cell or to a material such as chemical waste/laboratory waste. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-II and IV-V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-II and IV-V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-II and IV-V.

The inventions of Group III and Groups IV-V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for reducing the effects of ionization radiation in soil, water, spill, process waste steam or in hospital waste.

The inventions of Group III and Groups I-II are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In

the instant case the process as claimed can be used to make other and materially different produces wherein the process involves a further step comprising adding the proteoliposome to a toxic compound residing in a bioreactor, soil, water or hospital waste.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26,

1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/16/05